

IN THE CLAIMS

1. (Currently Amended) A method for determining the presence of Bence Jones Protein in an uncentrifuged urine sample, comprising the steps of:

~~providing a conjugate pad comprising a chromogenic mobile specific binding partner for binding to analyte;~~

providing a chromatographic test strip comprising a matrix through which a an uncentrifuged urine test sample can flow by capillary wherein said chromatographic test strip comprises at least ~~two~~one reaction sites~~ite~~;

wherein said at least one reaction site comprises a first reaction site comprising a first immobilized specific binding reagent capable of immobilizing said chromatographic mobile specific binding partner in relation to the presence of ~~the analyte~~ Bence Jones Proteins in the urine sample;

~~a control reaction site comprising a second immobilized specific binding reagent capable of immobilizing a chromogenic mobile specific binding partner;~~

~~contacting said conjugate pad to said chromatographic test strip such that said first reaction site lies between said conjugate pad and said control reaction site;~~

~~contacting said chromatographic test strip with an absorbent pad such that said absorbent pad is positioned opposite said conjugate pad and such that both said first reaction site and control reaction site lie in between said conjugate pad and said absorbent pad;~~

developing said chromatographic test strip by applying an uncentrifuged urine sample suspected of containing said analyte Bence Jones Proteins thereto thereby allowing the same to contact said ~~chromogenic mobile specific binding partner to form an analyte/chromogenic mobile specific binding partner complex~~ chromatographic test strip whereby capillarity carries the urine test sample along the strip to the first reaction site containing said first immobilized specific binding reagent ~~and said control reaction site comprising said second immobilized specific binding partner; and~~

determining the presence of analyte Bence Jones Protein in the urine test sample by viewing said first reaction site;

~~determining if migration has occurred by detecting the presence of analyte/chromogenic mobile specific binding partner complex at said control reaction site;~~

~~wherein detection may be made by observation of color at the control reaction site.~~

2. (Currently Amended) The method of claim ~~1~~ 41 wherein the step of providing a chromatographic test strip further comprises providing a second reaction site positioned in-between said first reaction site and said control reaction site wherein said second reaction site is capable of immobilizing said chromogenic mobile specific binding partner in relation to the presence of said analyte Bence Jones Protein in said urine, wherein said analyte Bence Jones Protein is selected from the group consisting of free and bound kappa light chains, and free and bound lambda light chains.

3. (Currently Amended) The method of claim 1, wherein said ~~analyte~~ Bence Jones Protein is selected from the group consisting of free and bound lambda light chains, free and bound kappa light chains, free kappa light chains, and free lambda light chains.
4. Cancelled.
5. (Currently Amended) The method of claim 1 ~~41~~, wherein said mobile specific binding partner is at least one conjugated monoclonal antibody.
6. (Currently Amended) The method of claim 1 ~~41~~, wherein said chromogenic mobile specific binding partner is selected from the group consisting of conjugated anti-free and bound kappa light chain antibody, and conjugated anti-free and bound lambda light chain antibody.
7. (Previously Amended) The method of claim 1 wherein said first immobilized specific binding reagent is selected from the group consisting of free and bound kappa light chains, free and bound lambda light chains, free kappa light chains, and free lambda light chains.
8. (Previously Amended) The method of claim 1 wherein said first immobilized specific binding reagent is selected from the group consisting of anti-free kappa light chain antibody, anti-free lambda light chain antibody, anti-free and bound kappa light chain antibody, and anti-free and bound light lambda light chain antibody.
9. (Currently Amended) The method of claim 1 ~~2~~, wherein said second immobilized specific binding reagent is Protein A.

10. (Currently Amended) The method of claim 1 further comprising providing a chromatographic test strip further comprising a second reaction site, wherein said second reaction site further comprises a ~~third~~ second immobilized specific binding reagent selected from the group consisting of anti-free and bound kappa light chain antibody, anti-free kappa light chain antibody, anti-free lambda light chain antibody, and anti-free and bound lambda light chain antibody.

11. (Currently Amended) The method of claim 1, wherein said assay is a sandwich assay and ~~the step of wherein~~ determining the presence of analyte Bence Jones Protein in urine further comprises visualization of a band at said first ~~and second~~ reaction site.

12. (Currently Amended) The method of claim ~~1~~ 41, wherein ~~the step of~~ determining the presence of analyte Bence Jones Protein in urine further comprises visualization of said first and said control reaction site, wherein the absence of band formation at said first reaction site indicates a positive result and the visualization of a band at said first reaction site indicates a negative result.

13. (Currently Amended) A device for the detection of analyte Bence Jones Protein in uncentrifuged urine, comprising:

~~a conjugate pad said conjugate pad comprising a chromogenic mobile specific binding partner capable of binding to analytes;~~

a chromatographic test strip comprising a matrix through which uncentrifuged urine can pass by capillary carrying said ~~mobile specific binding partner and said analyte~~ Bence Jones Protein, wherein said chromatographic test strip comprises ~~three~~ two reaction sites,

a first reaction site comprising a first immobilized specific binding reagent capable of immobilizing ~~said chromogenic mobile specific binding partner~~ bound to a first Bence Jones Protein analyte in the urine sample, and

a second reaction site comprising a second immobilizing specific binding reagent capable of immobilizing ~~said chromogenic mobile specific binding partner~~ bound to a second Bence Jones Protein analyte in the urine sample;

~~a third control reaction site comprising a third immobilizing specific binding partner capable of immobilizing said mobile specific binding partner;~~

~~an absorbent pad disposed upon said chromatographic test strip such that said absorbent pad is positioned opposite said conjugate pad and such that said first reaction site, second reaction site, and said third reaction site lie in between said conjugate pad and said absorbent pad.~~

14. Cancelled.

15. (Previously Amended) The device of claim 13, wherein said first analyte is selected from the group consisting of free kappa light chains, free and bound kappa light chains, free lambda light chains, and free and bound lambda light chains.

16. (Previously Amended) The device of claim 13, wherein said chromatographic test strip is a porous material.

17. (Previously Amended) The device of claim 13, wherein said chromatographic test strip is a nitrocellulose or nylon.

18. (Currently Amended) The device of claim ~~13~~ 42, wherein said chromogenic mobile specific binding partner is at least one conjugated monoclonal antibody.
19. (Currently Amended) The device of claim ~~13~~ 42, wherein said chromogenic mobile specific binding partner is a conjugated monoclonal antibody cocktail.
20. (Currently Amended) The device of claim ~~13~~ 42, wherein said chromogenic mobile specific binding partner is selected from the group consisting of conjugated anti-free and bound kappa light chain antibody, conjugated anti-free and bound lambda light chain antibody, conjugated anti-free kappa light chain antibody, and conjugated anti-free lambda light chain antibody.
21. (Previously Amended) The device of claim 13 wherein said first immobilized specific binding reagent is selected from the group consisting of anti-free kappa light chain antibody and anti-free lambda light chain antibody.
22. (Currently Amended) The device of claim ~~13~~ 42, wherein said third immobilizing specific binding partner is Protein A.
23. (Previously Amended) The device of claim 13, wherein said second immobilizing specific binding reagent is selected from the group consisting of anti-free and bound kappa light chain antibody, and anti-free and bound lambda light chain antibody for the determination of the presence of whole antibody.
25. (Currently Amended) The device of claim ~~13~~ 42, wherein the visualization of the control reaction site indicates that immunological chemicals have migrated through said chromatographic test strip.

26-32. Cancelled

33. (Currently Amended) A kit for determining the presence of analyte in urine, comprising:

the test strip of claim ~~26~~ 13; and

a reaction tube for mixing said test strip with an aliquot of uncentrifuged urine.

34. (Original) The kit of claim 33 wherein said reaction tube delivers between 100 microliters of urine to 1.0ml preferably 300 microliters of urine to said test strip.

35. (Previously Amended) The kit of claim 33 wherein said reaction tube further comprises a cap for facilitating disposal of biological waste.

36-38. Cancelled

39. (Currently Amended) The method of claim 1 wherein ~~the step of~~ determining the presence of analyte Bence Jones Protein in the urine test sample by viewing said first reaction site further comprises detecting the presence of ~~an~~ a Bence Jones Protein analyte/chromogenic mobile specific binding partner complex at said first reaction site.

40. (Currently Amended) The method of claim 1 wherein ~~the step of~~ determining the presence of analyte Bence Jones Protein in the urine test sample by viewing said first reaction site further comprises detecting the absence of ~~an~~ a Bence Jones Protein analyte/chromogenic mobile specific binding partner complex at said first reaction site.

41. (New) A method in accordance with claim 1, wherein said uncentrifuged urine and/or said chromatographic test strip is provided with a chromogenic mobile specific

binding partner for binding to Bence Jones Proteins and further comprising a control reaction site comprising a second immobilized specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner, wherein said method further comprises allowing said uncentrifuged urine to contact said chromogenic mobile specific binding partner to form an analyte/chromogenic mobile specific binding partner complex determining if migration has occurred by detecting the presence of analyte/chromogenic mobile specific binding partner complex at said control reaction site, wherein detection may be made by observation of color at the control reaction site.

42. (New) A device in accordance with claim 13, wherein said first and second reaction sites comprise immobilized specific binding reagents capable of immobilizing a chromogenic mobile specific binding partner bound to a Bence Jones Protein analyte in the uncentrifuged urine sample, and wherein the device further comprises a third, control reaction site comprising a third immobilizing specific binding partner capable of immobilizing said mobile specific binding partner.